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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,518	09/22/2003	Andre Stamm	107664.115 US11	5827

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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/665,518	STAMM ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/26/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of Applicant's Response, Arguments/Remarks after Non-Final Office Action and the Information Disclosure Statement (IDS), all filed 01/26/2007 is acknowledged.

Claims 1-45 are pending in this action. No claims have been amended in this response. Claims 1-45 remain rejected.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curtet *et al.* (US Pat. No. 4,895,726) in view of Kerč *et al.* (US Pat. No. 6,042,847).

The instant invention is drawn to a capsule comprising a fenofibrate composition, said fenofibrate composition comprising fenofibrate, at least one hydrophilic polymer and at least one disintegrating agent, wherein the weight ratio of fenofibrate to hydrophilic polymer is between 1:10 and 4:1.

Curtet *et al.* ('726) teach a fenofibrate composition which is presented in the form of gelatin capsules and which is especially useful in the oral treatment of hyperlipidemia and

hypercholesterolemia, whereby the composition comprises fenofibrate particles in combination with a solid surfactant, wherein the fenofibrate and solid surfactant have been co-micronized (see reference column 1, line 1 - col. 2, line 68) and Claim 1.

Curtet *et al.* teach that the recommended amount of fenofibrate is about 200 mg per therapeutic unit and the mean particle size of the fenofibrate is less than 15 microns, preferably less than 10 microns and particularly preferably less than 5 microns (col. 1, lines 50-66). Curtet et al. teach that to obtain a powder which can be formulated into gelatin capsules, conventional filling, dispersing and flow-enhancing excipients, for example, lactose, starch, polyvinylpyrrolidone and magnesium stearate may be added to the co-micronizate of fenofibrate and solid surfactant (col.1, line 67 through col. 2, line 4). Suitable disintegrants disclosed include crosslinked polyvinylpyrrolidone (col. 2, lines 36-37) and starch (col. 3, line 28).

Curtet *et al.* teach a method for preparing a therapeutic composition comprising fenofibrate and a solid surfactant, which comprises (i) intimately mixing and then co-micronizing the fenofibrate and the solid surfactant, (ii) adding lactose and starch to the mixture obtained, (iii) converting the whole to granules in the presence of water, (iv) drying the granules until they contain no more than 1% of water, (v) grading the granules, (vi) adding polyvinylpyrrolidone and magnesium stearate to the graded granules and (vii) filling gelatin capsules with the mixture obtained in stage (vi). The mean particle size of the micronized mixture obtained is less than 15 microns (μm) (see reference column 2, lines 5-20).

Curtet *et al.* teach overlapping amounts of fenofibrate and the hydrophilic polymer-polyvinylpyrrolidone, wherein the fenofibrate is present in an amount of 200 mg per therapeutic unit (col. 1, lines 50-51) and the polyvinylpyrrolidone is contained in an amount of 7 mg (col. 3,

lines 21-32). The fenofibrate/solid surfactant mixture granules have a mean particle size of less than 15 μm (col. 1, lines 61-66).

According to Curtet *et al.*, it is known that the micronization of an active principle is capable of improving the dissolution of the said active principle in vivo, and hence its bioavailability. It is also known that the addition of a surfactant excipient to a formulation of an active principle is capable of improving the absorption and consequently the bioavailability of the said active principle (col. 1, lines 28-34).

The fenofibrate composition can be presented in the form of gelatin capsules, which are especially useful in the oral treatment of hyperlipidemia and hypercholesterolemia (col. 1, lines 44-49).

Example 1 at column 2 demonstrates gelatin capsules containing drug, fenofibrate (20.0 kg), sodium laurly sulfate (0.7 kg), α-lactose monohydrate (10.1 kg), pregelatinized starch, disintegrant - cross-linked polyvinylpyrrolidone (0.7 kg) and magnesium stearate (0.5 kg).

Curtet *et al.* teach that the weight ratio of surfactant/fenofibrate will be between about 0.75/100 and 10.5/100 (col. 1, lines 59-60). Curtet *et al.* do not explicitly teach the claimed weight ratio of the fenofibrate/hydrophilic polymer. Curtet *et al.* also do not teach the claimed fenofibrate amounts/ranges. However, it is the position of the Examiner that Applicants have not demonstrated any unexpected or superior results attributable to the claimed weight ratio of the fenofibrate/polymer, nor the amounts of fenofibrate claimed, nor the particular hydrophilic polymer. Suitable or effective weight ratios of drug/polymer, surfactant/polymer and amounts ranges of drug/polymer could be determined by one of ordinary skill in the pharmaceutical art

through routine or manipulative experimentation to obtain optimal results, as these are indeed variable parameters attainable within the art.

Curtet *et al.* teach a hydrophilic polymer, such as polyvinylpyrrolidone. Curtet *et al.* do not teach the hydrophilic polymer being hydroxypropylcellulose.

Kerč *et al.* (847) teach a three-phase fenofibrate pharmaceutical formulation for daily peroral application, wherein the composition comprises cellulose ethers, such as hydroxypropylcellulose and whereby the compositions can be in the form of tablets or capsules. According to Kerč *et al.,* the cellulose ethers act as an agent for sustained and controlled release of the active ingredient (see reference column 1, lines 18-22); (col. 6, lines 4-28).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate hydrophilic polymers, such as hydroxypropylcellulose, as taught by Kerč *et al.* within the fenofibrate compositions of Curtet *et al.* One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Kerč *et al.* explicitly teach a fenofibrate composition that comprises cellulose ethers, such as hydroxypropylcellulose that act as an agent for sustained and controlled release of the active ingredient. The expected result would be an improved, sustained or controlled release capsular fenofibrate composition for the treatment of high cholesterol levels.

Given the explicit teachings of Curtet *et al.* and Kerč *et al.*, the instant invention, when taken as a whole, would have been deemed *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed 01/26/07 have been fully considered but they are not persuasive.

Rejection under 35 U.S.C. 103(a) of claims 1-45 over Curtet ('726) in view of Kerč *et al.* ('847):

Applicant argued, "Neither Curtet nor Kerc disclose the claimed capsules having the claimed fenofibrate to polymer ratio of between 1:10 and 4:1. Neither Curtet nor Kerc provide any motivation to drastically reduce the weight ratio of fenofibrate to cross-linked PVP of 29:1 in Curtet to fall within the claimed range of fenofibrate to polymer of between 1:10 and 4:1. Kerc does not provide any motivation to modify the weight ratios of the components in Curtet to arrive at the claimed weight ratios."

Applicant's arguments have been considered, but were not persuasive. Admittedly, while the prior art teaches ratios of fenofibrate to polymer that are slightly different than that claimed, the Examiner points out that the differences in ratio do not impart a patentable distinction over the explicit reference teachings. Suitable ratios could be determined by one of ordinary skill in the art through routine or manipulative experimentation to obtain optimal results, as these are variable parameters attainable within the art. Furthermore, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller,* 220 F.2d 454, 456, 105

USPQ 233, 235 (CCPA 1955). In the instant case, the prior art teaches a similar capsule as claimed, which is comprised of the same components (fenofibrate, polymers) and used for the same purpose (i.e., lowering cholesterol) as that of the Applicant. The determination of effective ratios is within the level of one of ordinary skill in the art.

The claims, at present, remain generic enough to read on the reference teachings discussed above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

Patent Examiner

Art Unit 1615

April 16, 2007

HUMERA N SHEIKH
PRIMARY EXAMINER

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